REMARKS

In an Official Action dated December 1, 2004, the Examiner rejected claims 45, 48-50, 69 and 72 as anticipated by Ridderheim 4,955,870. In addition, the Examiner rejected the pending claims under obviousness-type double patent over a number of Applicants' patents alone or in combination with Alter 4,919,652. Applicants request that the Examiner reconsider the rejections in light of the following discussion.

Claims 45, 48-50, 69 and 72 are patentable over Ridderheim 4,955,870

As discussed below, Ridderheim is not directed to a device having a needle assembly that includes a biasing element, which is connectable to a barrel. Instead, Ridderheim '870 discloses a device in which the spring is located in the plunger, not in the needle assembly. Therefore, the Ridderheim device requires an exacting connection between the plunger tip and the needle hub to ensure retraction, and complicates the production of the device.

Referring to Fig. 1, Ridderheim discloses a syringe having a barrel 16 and a plunger 14 that slides within the barrel. The plunger includes a frangible tip 84 that is connected a spring 56 in the plunger. The spring 56 is maintained in tension so that the spring biases the plunger tip 84 in tension.

A needle assembly 12 attached to the forward end of the barrel 16 has a mating means 86 configured to cooperate with a protrusion 92 on the end of the plunger tip 84. The needle assembly includes a plug 64 connected to the barrel 16 that is detachably connected to the mating means 86 of the needle assembly 12. In this way, at the end of the injection stroke, the protrusion 92 on the plunger engages the mating means 86 of the needle assembly. By pushing further on the plunger, the matting means 86 and needle are ripped from the plug 64 freeing the needle for retraction. At the same time, the tip of the plunger is fractured, so that the needle is retracted into the plunger.

In contrast to the Ridderheim structure, Applicants' device includes a needle assembly in which the needle assembly is separate and can be attached to the barrel prior to use. Further, in Applicants' device, the needle assembly includes the biasing element, rather that having the biasing element disposed in the plunger.

There are numerous disadvantages to the Ridderheim structure. First, by using a spring under tension, the plunger becomes much more complicated to manufacture. The tip cannot be molded integrally with the plunger stem, because doing so would make it impossible to attach the spring to the plunger and the plunger tip. Furthermore, the plunger tip must be held in a delicate balance. The connection between the plunger tip and the plunger stem must be sufficient to withstand the tension of the spring and the hydraulic forces acting against the tip during an injection, while at the same time the tip must be able to break free from the plunger easily to cause retraction.

In addition to these complications, the Ridderheim device relies on a connection between the plunger tip and the needle mating means 86. If the connection fails, the needle will not retract. More specifically, at the end of the injection stroke, the plunger tip is fractured from the plunger stem, and the mating means 86 and needle are broken from the needle plug 64. As soon as the plunger tip is fractured, the tip will retract regardless of whether the needle is attached. In other words, it the plunger tip does not adequately connect with the mating means 86 the needle will not retract. Therefore, the system must ensure a significant connection between the plunger tip and the mating means 86, which must withstand the force of the needle being suddenly jerked rearwardly upon retraction.

If any of the foregoing aspects of the Ridderheim device does not operate properly, the needle does not retract. In other words, the first end of the spring and the outer end of the plunger must stay connected. The second end of the spring must stay

connected to the plunger tip. The plunger tip must stay connected to the plunger stem before use and during an injection. The plunger tip must break from the plunger stem at the end of an injection. The needle must break from the plug 64 at the end of an injection and the plunger tip must engage the needle mating means 86 and securely hold the mating means during retraction. This is a lot of critical requirements for a device. Therefore, it would be difficult to expect the device to reliably operate on mass production scale, and even more difficult to do so inexpensively.

Further still, near the end of an injection stroke, the protrusion 92 on the end of the plunger begins to block the end of the needle before all of the fluid is expelled from the barrel. Therefore, the needle 12 must include a complicated series of holes 80 to allow the fluid in the barrel to flow through the needle when the plunger nears the end of an injection.

As can be seen, there are numerous disadvantages to the Ridderheim structure that complicate the manufacture, assembly and reliability of the device. Furthermore, there is nothing in Ridderheim that teaches or suggests altering the Ridderheim structure to be like Applicants' structure. In fact, there is nothing in Ridderheim that suggests addressing the advantages of having a structure like Applicants'. Specifically, Applicants' structure allows the user to select the desired needle and attach the needle assembly to the barrel. Ridderheim does not allow the user to do this. As shown in Fig. 1, the Ridderheim structure requires that the needle 12 be threaded into the barrel from the *inside*. See Fig. 2. It is difficult to imagine how a medical professional could reach down through the inside of the barrel and screw a needle assembly into the barrel prior to use.

Turning now to the claim language, features that distinguish Applicants' device from the Ridderheim device are reflected in the claims. Specifically, claim 45 and 69 recite a medical device having a hollow barrel having a forward end and a first

connector, and a needle assembly having a second connector that is cooperable with the first connector to attach the needle assembly to the barrel. Further, in claim 45 the needle assembly includes a hub having a cavity and a biasing element disposed within the cavity that biases the needle toward the retracted position. In claim 69, the needle assembly includes a base having a hollow portion and at least a portion of the biasing element is disposed within the hollow portion.

As discussed above, the Ridderheim device does not include a needle assembly that has a biasing element; the biasing element is in the plunger. Since this difference leads to significant advantages over the Ridderheim and since Ridderheim does not teach or suggest such features, Applicants request that the Examiner reconsider the rejection of claims 45 and 69 over Ridderheim, along with dependent claims 48-50 and 72.

Double-Patenting Rejections

Applicants request that the Examiner reconsider the rejection of claims 45-47, 50-53, 56-58, 60-64 and 66-73 over U.S. Patent No. 5,188,599. As discussed below, there are several patentable distinctions between the claims of the '599 patent and the pending claims.

For instance, claims 45, 51 and 63 specifically recite that the barrel includes a first connector and the needle assembly includes a second connector that is cooperable with the first connector to connect the needle assembly to the barrel. The '599 claims recite a spring holding means that is attachable to the barrel, however, the '599 claims do not specify connectors on a needle assembly and the barrel. Instead, the '599 claims are broad enough to cover a spring housing that is somehow attached to the barrel without separate connectors. In other words, the '599 claims are broad enough to cover a structure in which the spring holding means is glued or welded to the

barrel during manufacture.

In the Official Action, the Examiner states that the '599 claims recite a connector in the form of barrel means. However, the claims state that the barrel means is "for holding injectable fluid". There is no recitation of a connecting means. Further, the Official Action states that the second connector is the spring holding means. However, again, there is not recitation that the spring holding means includes a connector.

In addition to the fact that the claims do not recite first and second connectors for attaching a needle assembly to a barrel, there are several other elements in the pending claims that are not suggested by claims 1-17 in the '599 patent. For instance, claims 45, 63 and 69 recite that the sharpened tip of the needle is disposed in the cavity of the plunger after retraction. The '599 patent claims simply recite that the needle is displaced into the cavity, which could mean all or part of the needle. Claim 45 further recites that the biasing element is displaceable relative to the base of the needle assembly. Claim 45 recites that the hub of the needle assembly has a cavity and claim 69 recites that the base of the needle assembly has a hollow portion. Claims 51and 75 recite that the needle is displaceable relative to the hub of the needle assembly. Claims 51 and 74 recite that the cover of the plunger is displaced into the cavity of the plunger. Claim 57 recites that the needle assembly is releasably connected to the barrel, which is contrary to the claims, which recite a spring holding means that is lockable to the barrel. Finally, claims 63 and71 recite a breakable connection releasably connecting the needle with the housing of the needle assembly. The claims of the '599 patent simply state that the tapered shoulders of the plunger engage the tapered shoulders of the hooks of the resilient legs to radially displace the legs, there is no recitation of a breakable connection between the needle and the housing.

In light of the different features that are recited in the pending claims that are not recited in claims 1-17 of the '599 patent, Applicants request that the Examiner reconsider the non-statutory double-patenting rejection of claims 45-73 over claims 1-17 of the '599 patent.

To ensure that all of the issues raised in the application are addressed in this response, Applicants are responding to the double-patenting rejection over patent nos. 4,994,034 and 5,407,431 by indicating an intention to file a terminal disclaimer relative to the 4,994,034 and 5,407,431 patents once the issues are resolved relative to the prior art and the double-patenting rejection over the '599 patent.

In light of the foregoing, Applicant requests that the Examiner reconsider the rejections in the previous Official Action. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

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Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of **THREE** months beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

June 1, 2005
Date of Certificate

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